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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/051,719	01/16/2002	Matthew T. Scholz	57338US002	8633
32692	7590	02/16/2005		
3M INNOVATIVE PROPERTIES COMPANY PO BOX 33427 ST. PAUL, MN 55133-3427			EXAMINER CHOI, FRANK I	
			ART UNIT 1616	PAPER NUMBER

DATE MAILED: 02/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/051,719	SCHOLZ ET AL.	
	Examiner	Art Unit	
	Frank I Choi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 10 January 2005.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-43 and 54-63 is/are pending in the application.
- 4a) Of the above claim(s) 22-24, 31-36 and 40 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-21, 25-30, 37-39, 41-43 and 54-63 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) 1-43 and 54-63 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date: _____
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>1/10/2005</u> .	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: _____.

DETAILED ACTION

In view of Applicant's arguments and declaration, Examiner withdraws the finality of the prior Office Action to apply new grounds of rejection herein.

Election/Restrictions

Claims 33,34 should be withdrawn as directed to a non-elected invention as said claims are dependent on claims 32 which has been withdrawn (Examiner assumes that "claim 35" is a typographical error and that claim 34 was intended to be dependent on claim 33). As such, 1-43 and 54-63 are currently pending with claims 22-24,31-36 and 40 withdrawn as directed to a non-elected invention. Claims 1-21, 25-30, 37-39, 41-43,54-63 are directed to the elected invention of Group I, and species of iodophor, lactic acid and acrylate polymer.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-21, 25-30, 37-39, 41-43,54-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kross et al. (US Pat. 5,618,841) in view of Brink et al. (US Pat. 5,173,291) and Beach (US Pat. 3,380,923) in further view of Talwalker et al. (US Pat. 5,462,714) and Richter et al. (US Pat. 6,379,685).

Kross teaches the antimicrobial compositions containing iodophores, lactic acid, surfactants and the formation of films incorporating the above to form protective barriers having viscosities generally in the range from about 200 to 3,000 centipoise, using a suitable polymeric

material which are known to those skilled in the art (See entire document, especially Columns 3-5, Column 6, lines 1-6, Examples I, II, II, IV, V).

Brink et al. teach that organic solvents such as ethyl alcohol or isopropyl alcohol are often used as solvent carrier, however, they can be irritating to skin tissue and are not suitable for use on sensitive tissue such as burn wound sites and mucosal tissue and that the vapors are often toxic and/or flammable (Column 1, lines 48-55). It is taught that increasing the water and bodily fluid resistance of topically applied antimicrobial agents increase the substantivity and length of activity and that compositions that can form a water insoluble film can, in addition to providing a long lasting antimicrobial activity, also provide a protective layer for sensitive tissue (Column 1, lines 36-48). A composition is taught which is water-based, nonflammable, nonirritating and form low tack or tack free films, comprising iodine as the antimicrobial agent, and a mixture of monomers, including acrylates, in which the relative water resistance of the ultimate film is determined by the selection of comonomers to be used with iodine complexing comonomer and by adjusting the ratio of water insoluble comonomers to water soluble comonomers (Column 4, lines 5-68, Column 5, lines 35-68, Columns 6,7). It is taught that the emulsifiers commonly used include amphoteric surfactants and that the pH of the emulsions may be adjusted by the appropriate acidic species (Column 8, lines 28-63). It is taught that the films may be removed by covering with a surgical drape which includes a pressure-sensitive adhesive layer and by removing the surgical drape the film that is contacted by the adhesive layer is also removed (Column 9, lines 55-61).

Beach teaches that amphoteric surfactants, containing amine and sulfate groups, are suitable for use in preparing iodophore germicides suitable for use in the diary industry (Columns 1, 2).

Talwalker et al. discloses that addition of buffering agents may result in loss of homogeneity due to iodophor precipitation and that providing sufficient amount of carrier, such as a non-ionic surfactant, will stabilize the iodophor (Column 5, lines 21-39). It is disclosed that the combination of acids, such as lactic acid, with iodine results in synergistic microbiocidal activity (Column 2, lines 15-27, Column 4, lines 3-13).

Richter et al. discloses that in personal care products, alpha-hydroxycarboxylic acids used at levels under 10% have shown to improve skin condition and that it is believed that application of these acidulants on the bovine teat skin would accelerate healing and that the preferred acid is lactic acid (Column 10, lines 26-48). It is disclosed that the pH is buffered to typically from 2.5 to 5.5 with the lower value being a limit to prevent excessive irritation on the teat surface and the upper limit to maintain the antimicrobial effect of the protonated carboxylic acids (Column 12, lines 55-68). It is disclosed that any acidulant and corresponding conjugate weak base could be used (Column 13, lines 1-3). It is disclosed that complexed iodines, unlike other antimicrobial agents, offer the advantage of being easily visible when applied to the teat (Column 16, lines 63-65). It is disclosed that the blend of acidulant and /or antimicrobial can be from 1-12 wt% and the buffer can be from 0-15 wt% (Column 17, lines 50-68, Column 18, lines 1-10).

The difference between the prior art and the claimed invention is that the prior art does not expressly disclose the combination of iodophor, lactic acid, an acrylate film-forming polymer, amphoteric surfactant and water. However, the prior art amply suggests the same as it

is known in the art to prepare film-forming compositions containing iodophore, lactic acid, film-forming polymers, including acrylate polymers, and surfactants, including amphoteric surfactants. Further, one of ordinary skill in the art would have been motivated to modify the prior art as above with the expectation that the combination would form an antimicrobial film suitable for use in the dairy field as a teat dip.

Examiner has duly considered Applicant's arguments but deems them unpersuasive.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 231 USPQ 375 (Fed. Cir. 1986). The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

Applicant argues that the polymer in Kross are not necessarily substantive. However, Applicant has not provide any evidence of the same. The arguments of counsel cannot take the place of evidence in the record. *In re Schulze*, 145 USPQ 716, 718 (CCPA 1965); *In re Geisler*, 43 USPQ2d 1362 (Fed. Cir. 1997) ("An assertion of what seems to follow from common experience is just attorney argument and not the kind of factual evidence that is required to rebut a prima facie case of obviousness."). Further, Brinks et al. discloses the advantages of choosing a polymer which provides substantivity.

Applicant argues that the concentration of organic acid buffer only overlaps at the 5 wt% value. However, Kross does not disclose that about 5% is the maximum. It only discloses that the desired amount is in the range of about 0.05 to 5% (Kross, Column 5, lines 29-32).

Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. *In re Susi*, 169 USPQ 423 (CCPA 1971). “A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use.” *In re Gurley*, 31 USPQ2d 1130, 1132 (Fed. Cir. 1994). Further, as indicated above Richter et al. discloses the use of acids at amounts greater than 5 wt%.

Further, in the case where the claimed ranges “overlap or lie inside ranges disclosed by the prior art” a prima facie case of obviousness exists. *In re Wertheim*, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 16 USPQ2d 1934 (Fed. Cir. 1990) (The prior art taught carbon monoxide concentrations of “about 1-5%” while the claim was limited to “more than 5%.” The court held that “about 1-5%” allowed for concentrations slightly above 5% thus the ranges overlapped.); *In re Geisler*, 43 USPQ2d 1362, 1365-66 (Fed. Cir. 1997) (Claim reciting thickness of a protective layer as falling within a range of “50 to 100 Angstroms” considered prima facie obvious in view of prior art reference teaching that “for suitable protection, the thickness of the protective layer should be not less than about 10 nm [i.e., 100 Angstroms].” The court stated that “by stating that suitable protection’ is provided if the protective layer is about’ 100 Angstroms thick, [the prior art reference] directly teaches the use of a thickness within [applicant’s] claimed range.”). Similarly, a prima facie case of obviousness exists where the claimed ranges and prior art ranges do not overlap but are close enough that one skilled in the art would have expected them to have

the same properties. Titanium Metals Corp. of America v. Banner, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985) (Court held as proper a rejection of a claim directed to an alloy of “having 0.8% nickel, 0.3% molybdenum, up to 0.1% iron, balance titanium” as obvious over a reference disclosing alloys of 0.75% nickel, 0.25% molybdenum, balance titanium and 0.94% nickel, 0.31% molybdenum, balance titanium.). Further, “where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” In re Aller, 105 USPQ 233, 235 (CCPA 1955) (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be *prima facie* obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%); see also In re Peterson, 65 USPQ2d 1379, 1382 (Fed. Cir. 2003) (“The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages”). The amount of about 5% of the hydroxyacid is disclosed to be antimicrobial, as such, one ordinary skill in the art would expect that higher amounts would also be antimicrobial.

Applicant argues that it is surprising that comprising at least about 5 wt% and particularly in excess of 5 wt% of hydroxyacids are substantially non-irritating to tissue. However, nothing in the art precludes the use of higher amounts of acid and the prior art, as indicated above, discloses that excessive irritancy itself can be prevented by buffering to an appropriate pH or the use of emollients or humectants (Richter et al., Column 13, lines 25-33, Column 12, lines 55-64) Applicant’s citation to Poucher’s Perfumes, Cosmetics and Soaps does not overcome the

rejection as said reference discloses the use of alpha-hydroxy acids at amounts up to 15% and that because of their low pH are supplied as buffered solutions of pH 4.5. As such, the irritancy of said acids is not surprising and methods of preventing said irritancy are within the skill of one ordinary skill in the art. As such, the fact that said acids can be irritating is insufficient to preclude one of ordinary skill in the art from using amounts of acids at greater than 5% and one of ordinary skill in the art would use higher amounts because of their antimicrobial activity.

Applicant argues that high concentrations of hydroxycarboxylic acid buffers would be expected to contribute to poor PSA-coated product adhesion, however, Applicant does not indicate what would be considered to be a high amount. The prior art disclose the formation of films which form a protective barrier with amounts of hydroxyacid in the amount of about 5%. Applicant alleges that certain hydroxycarboxylic acid buffers in combination with substantive film foaming polymers still allow sufficient PSA-coated product adhesion and good substantivity. However, the claims claim hydroxycarboxylic in general, as such, the alleged evidence does not appear commensurate with the scope of the claims. In any case, Richter et al. recognizes that acids have an effect on the polymer film and that adjustments can be made to account for the hydrophilic components (Richter et al., Column 11, lines 64-68, Column 12, lines 1-35).

Applicant is incorrect that the Kross does not disclose the use of a surfactant. The IGEPAL CO-720 does not form the iodophor, the iodophor is already premade. The IGEPAL CO-720 is added to the iodophor concentrate. See Kross at Column 3, lines 28-32. Again, Applicant's focus on a disclosed embodiment and Kross et al. is insufficient to overcome the rejection as the rejection is based on the combination of references and the claimed invention

need not be expressly disclosed in any single or all of the references. Similarly, there is no requirement that Brink et al or Beach has to disclose high amounts of hydroxycarboxylic acid buffer. Further, the motivation to combine Beach is that Beach discloses that amphoteric surfactants are suitable for use in preparing iodophors.

Examiner has duly considered the Scholz declaration, however, said declaration does not overcome the rejection herein. In the first instance, Examiner notes that instead of just adding additional acid, the experiments add both acid and sodium phosphate. In any case, the problem of instability due to the addition of buffering compounds is recognized in the art and methods of preventing the same are disclosed (See Talawalker et al. above). As such, one of ordinary skill in the art would be able to adjust the composition in Brink et al. to account for any instability which may be caused by addition of a buffer in the amounts desired.

As such, contrary to Applicant's arguments the combined teachings of the prior art do disclose composition falling within the scope of the claimed invention or close enough that one of ordinary skill in the art would expect them to have the same properties. Further, the problems cited by Applicant are recognized by the prior art, as well, as methods for alleviating said problems.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed.

Art Unit: 1616

Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-21, 25-30, 37-39, 41-43, 54-63 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7, 16-25, 27, 29-44, 47-60 of copending Application No. 10/922,262 or claims 1-7, 16-25, 27, 29-44, 47-59 of US Pat. 6,838,078 in view of Kross et al. (US Pat. 5,618,841), Brink et al. (US Pat. 5,173,291) and Beach (US Pat. 3,380,923) in further view of Talwalker et al. (US Pat. 5,462,714) and Richter et al. (US Pat. 6,379,685).

The cited claims of the above-mentioned application teach a film forming composition comprising polymer containing a hydrophobic polymer, such as methacrylic, water, a surfactant, such as an amphoteric surfactant, which can contain an antimicrobial agent, such as iodophor, and a hydroxy-carboxylic acid buffer, such as lactic acid.

Kross et al. (US Pat. 5,618,841), Brink et al. (US Pat. 5,173,291), Beach (US Pat. 3,380,923), Talwalker et al. (US Pat. 5,462,714) and Richter et al. (US Pat. 6,379,685) are cited herein for the same reasons as above and are incorporated herein to avoid repetition.

The difference between the claims of the cited application and the claimed invention is that the prior art does not expressly disclose the combination of iodophor, lactic acid, an acrylate film-forming polymer, amphoteric surfactant and water. However, the prior art amply suggests the same as it is known in the art to prepare film-forming compositions containing iodophore,

Art Unit: 1616

lactic acid, film-forming polymers, including acrylate polymers, and surfactants, including amphoteric surfactants. Further, one of ordinary skill in the art would have been motivated to modify the prior art as above with the expectation that the combination would form an antimicrobial film suitable for use in the dairy field as a teat dip.

Therefore, the claimed invention, as a whole, would have been an obvious modification of the claims of said copending US application or US Patent to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references and the claims of said application.

This is a provisional obviousness-type double patenting rejection with respect to the copending US application. The rejection over the US Patent is not provisional.

Conclusion

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.

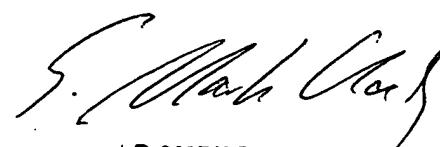
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a flexible schedule. However, Examiner may generally be reached Monday-Friday, 8:00 am – 5:30 pm (EST), except the first Friday of the each biweek which is Examiner's normally scheduled day off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. Gary Kunz, can be reached at 571-272-0887. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

FIC

February 14, 2005



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